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The study on thyroid status among newborns in Jaffna District in Sri Lanka

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Abstract

Iodine is an essential nutrient for the production of thyroid hormones triiodothyronine (T_3) and thyroxine (T_4). A woman needs more iodine during pregnancy to maintain normal metabolism as well as to meet the requirements of T_4 and iodide transfer to the fetus. Objective of this study was to assess the thyroid status among newborns in Jaffna District, because similar studies conducted nationally, but not in Jaffna and no data is available about the thyroid status of the neonates. Randomly selected 477 newborns in six Medical Officers of Health (MOH) Divisions out of twelve were studied.Blood spots were taken from the neonates within the one week of delivery on specified filter paper and thyroid stimulating hormone (TSH) was assayed by using enzyme-linked immunosorbent assay(ELISA)/Radioimmunoassay (RIA) technique depending on availability of the kits in the laboratory. Among the total newborns, 239 were males (50.5%). Mean birth weight (BW) of them was 3031.5(±432.6) g, while the mean length was 51.1 (±2.1) cm. BW of males ranged from 1.7 to 5.0 Kg and of females from 1.5 to 4.35 Kg. Length of the newborns ranged from 45.0 to 58.0 cm for males and from 44.0 to 57.0 cm for females. The low birth weight (LBW), normal birth weight (NBW) and higher birth weight (HBW) were 11.3 (n=54), 88.5 (n=422) and 0.2 % (n=1) respectively. Mean neonatal blood spot TSH concentration was 9.8 (±2.1) mIU/L, and ranged from 1.00 to 53.46 mIU/L. Neonatal TSH level of the entire blood spot was categorized as > 20 mIU/L and < 20 mIU/L and the blood spot TSH > 20 mIU/L was considered as positive for congenital hypothyroidism. Among the newborns, 18% (n=86) of them were identified as positive with 10 % males and 8% females. Only one newborn was diagnosed as being congenitally hypothyroid (serum TSH >9.8 mIU/L and free T_4< 10 pmol/L) with very high blood spot TSH value of 360.91 mIU/L. Further, a higher prevalence (37.7%) of neonates with blood spot TSH >5 mIU/Lwas observed in this study.

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*Keywords:*Thyroid hormone; congenital hypothyroidism; newborns; birth weight

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1. Introduction

Iodine is an essential nutrient for the production of the thyroid hormones, triiodothyronine (T_3) and thyroxine (T_4). A woman needs more iodine during pregnancy to maintain normal metabolism as well as to meet the requirements of T_4 and iodide transfer to the fetus. An insufficient supply of thyroid hormones to the developing brain of the fetus can result in congenital anomalies and intellectual impairment[1]. Further, symptoms and signs of congenital hypothyroidism (CH) are often non-specific unless tested biochemically, and CH will be frequently overlooked, resulting in irreparable neurological damage caused by thyroid hormone deficiency during this crucial period of brain development. For early detection and implementation of thyroid hormone therapy, systematic screening programs for neonatal thyroid function were introduced in many countries in the early 1970s[2,3]. The initial screening method was measurement of T_4 by heel-prick blood spots sample. This has been superseded by measurement of thyroid stimulating hormone (TSH) level in most programmes around the world including in Sri Lanka. The major inconvenience in measurement of serum TSH level is that it is unable to detect central (hypothalamic or pituitary) hypothyroidism, a rare disorder occurring in approximately 1 in 20 000 neonates, which can be picked up only by doing T_4 test. Serum TSH assay can detect the subclinical or transient primary hypothyroidism that can be missed by T_4 assay in screening programs for CH[4]. The incidence of CH has been reported as 1 in 1500 to 1 in 2000 live births in Southern part of Sri Lanka between 2011 and 2012[5]. Decline in incidence may be due to the improved knowledge of pregnant mothers on iodine nutrition by health education in antennal clinics. Only few studies have been published on the thyroid statusof the newborns in Sri Lanka by assessing the neonatal TSH level. Further, after the implementation of the universal salt iodization program in Sri Lanka there have not been any published data on thyroid function among the newborns. Also, iodine supplementation during pregnancy is not a routine practice in Sri Lanka. Policy makers might be thinking that salt iodization is adequate to provide optimum iodine nutrition to the population. Therefore, this study was carried out to assess the thyroid status among newborns in Jaffna District.Although some similar studies have been conducted nationally, there are no data available about the thyroid status of the neonates in Jaffna district.

2. Methodology

Four hundred and seventy seven newborns of the randomly selected pregnant mothers in six (Jaffna, Uduvil, Nallur, Kopay, Karaveddy and Kays) Medical Officers of Health (MOH) Divisions out of twelve were included for this study during the period 2012/2013. Newborns were selected randomly with probability proportion to the number of deliveries occurred in the previous year of this study conducted. Ethical approval was obtained from Ethical Review Committee of the Faculty of Medicine, University of Jaffna. Results were presented by using descriptive statistics as mean (±standard deviation), percentage and frequency. Simple linear regression analysis was used to test the correlations between blood spot TSH and BW of the newborn. Weight of the newborn was measured by digital infant scale to the precision of 10 g with wearing nappies or only light clothing. First the “zero” level of scale was adjusted. Next the newborn was put on the weighing pan of the digital infant scale. The weighing scale was checked every morning prior to the use. The recumbent length of the infants was measured by using portable infantometer (SECA 417, Germany) with a precision of 0.1 cm. Further, examination was carried out and a heel prick blood spot (by filter paper) was collected from the neonate prior to the discharge. If the blood spot were not obtained from the newborn before the discharge from the hospital, spots were collected through home visits within a week of delivery. The cut- off values for TSH were decided depending on the age of the newborn at the time of blood spot collection and it was 40.0 mIU/L upto 48 hrs (i.e., Day 2) and 20.0 mIU/L after 48 hrs of life (i.e., Day 3 onwards). These values were based on the analysis of a pilot study done at Southern Province of Sri Lanka (Hettiarachchi&Amarasena, 2014). The blood spot TSH analyses were done using the IMMUCHEM™ NEONATAL TSH-MW ELISA (bulk kit −20 plates) and radioimmunoassay (RIA) kits (500 tubes kit) provided by MP Biochemicals, USA on availability of the kits in the laboratory. Once a positive case was found a repeat test was performed to confirm results. For that, the parents were contacted immediately through telephone in order to get a serum sample for the confirmation of the disease. Both serum TSH and free T_4 were determined in these newborns using respective enzyme-linked immunosorbent assay (ELISA) kits provided by the MP Biochemicals, USA. CH was confirmed if serum TSH >9.8 mIU/L and free T_4< 10 pmol/L Data were presented as descriptive statics mean± SD, range, frequency and percentage. The coefficients of variation of the intra-assays was 5.5%, whereas inter-assay

was 4.5%. The lower limit of detection was 0.01 μIU/mL. Intra-assay precision was below 0.50% and inter-assay coefficient variation was 2.0%.

3. Results

3.1 *Characteristics of the newborns*

Newborns characteristics and their thyroid status are given in Table 1. Among the 477 newborns, 239 were males (50.5%). Mean BW of them was 3031.5(±432.6) g, while the mean length was 51.1 (±2.1) cm. BW of males ranged from 1.7 to 5.0 Kg and of females from 1.5 to 4.35 Kg. Length of the newborns ranged from 45.0 to 58.0 cm for males and from 44.0 to 57.0 cm for females. BW was categorized into LBW (<2500 g), NBW (2500-4500 g) and HBW (>4500 g). The LBW, NBW and HBW were 11.3 (*n*=54), 88.5 (*n*=422) and 0.2 % (*n*=1) respectively. Further, among the total of 477 newborns, 68.1 % were normal delivery and rest of them via caesarean.

3.2 *Neonatal TSH and congenital hypothyroidism*

Mean neonatal blood spot TSH concentration of 477 subjects was 9.8 (±2.1)mIU/L, and ranged from 1.00 to 53.46 mIU/L. According to the guidelines of International Atomic Energy Agency (IAEA), neonatal TSH level of the blood spot was categorized > 20 mIU/L and < 20 mIU/L. The serum TSH > 20 mIU/L is considered as positive for congenital hypothyroidism. Among the newborns, 18% (n86) of them were identified as positive with 10 % males and 8% females. The recall rate was less than 1.0 %, and only one newborn was diagnosed as being congenitally hypothyroid with very high TSH value of 360.91 mIU/L during the study period from May 2012 to December 2013. CH was confirmed finally, newborn was referred for treatment to a paediatrician. Neonatal blood spot TSH level was not significantly correlated with BW of the newborn (p=0.11, r=0.78).

Table 1: Newborns 'characteristics and blood spots TSH level

Newborn's parameter		**Male**	**Female**	**Over all**
			% (Number)	
Sex		50.5 (239)	49.5 (238)	100 (477)
Birth Weight (Kg)	mean(range)	3.06 (1.70 -5.00)	3.00 (1.50 – 4.35)	3.03 (1.50 – 5.00)
Length (cm)	mean(range)	51.2 (45.0-58.0)	50.9 (44.0-57.0)	51.1 (44.0-58.0)
LBW	% (n)	5.0 (24)	6.3 (30)	11.3 (54)
NBW	% (n)	46.3 (221)	42.2 (201)	88.5 (422)
HBW	% (n)	0.2 (1)	0 (0)	0.2 (1)
Blood spot TSH	<20.0 mIU/L	40.0 (191)	42.0 (200)	82.0 (391)
	>20.0 mIU/L	10.0 (48)	8.0 (38)	18.0 (86)

3. Discussion

Neonatal blood spot TSH level of hypothyroid baby was very high (361.9 mIU/L) and it was detected by blood spot analysis. This assay may be used to identify neonates with congenital hypothyroidism caused by lack of maternal iodine nutrition. The reason for this association would be the lack iodine intake during pregnancy and may have induced the elevated TSH in neonates. In Sri Lanka, the incidence rate of CH is much higher when compared to the

rest of the countries in South Asia, although published reports have been limited nationally. In a study conducted in Southern part of the country in 2011- 2012, a total of 78,167 newborns (99.0% of live births) were screened for CH. The incidence of primary CH among screened newborns was 1:1682 and the number of true positive cases and consequently the incidence rate of CH increased from 1:1800 in 2011 to 1:1500 in 2012[5]. The frequency of permanent CH varies in different countries. Recent studies in India expressed a prevalence of CH as approximately 1:1100[6]. In Iran the incident rate of CH was 1 in 895 live births, whereas the corresponding rates in Tehran and Damavand were about 1 in 950[7]. Another study conducted with 93381 neonates in Iran showed that the prevalence of CH was l in 349 live births. But, the worldwide the prevalence of CH was reported as 1 in 3000–4000 live births[7].But, this present study indicated that higher prevalence rate of CH observed in Jaffna District. However, this study had some potential limitations. The sample size was relatively small and may not be adequate for calculation of a true prevalence of CH. Therefore, these results need to be reassessed with a larger number of study samples in same study area. Considering this high incidence rate of CH, availability of low cost therapy and a robust screening test like blood spot TSH, is highly desirable to start a screening program in entire Northern Province to prevent the most preventable cause of mental sub normality.

Further, utilization of neonatal TSH is an attractive method because it is assumed that the thyroid of the newborn is very sensitive to iodine status and even mild iodine deficiency during pregnancy will cause an increase in neonatal TSH secretion. In addition in countries where such screening programme exists, the utilization of neonatal TSH levels does not imply an extra cost. Unfortunately in most of the regions where iodine deficiency is severe such screening programs are usually lacking. In Sri Lanka however the situation is different because there are two screening centres in Central Province and Southern Province using two different assay methods (ELISA and RIA). Despite this heterogeneity and after applying correction factors for time sampling, the centre showed concordant values indicating a low frequency of TSH >20 mIU/L.

4. Conclusion

The prevalence of CH was high in Jaffna District and higher prevalence (37.7%) of neonates with blood spot TSH >5 mIU/Lwas observed in this study.

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